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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/457,421	12/07/1999	ALAN A. DAVIS	AHP92038-2-C	7663
25291	7590	04/21/2005	EXAMINER	
WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			LE, EMILY M	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/457,421

Applicant(s)

DAVIS ET AL.

Examiner

Emily Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26 and 28-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26 and 28-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

*HL*

## DETAILED ACTION

### *Status of Claims*

1. Claims 1-25, 27 and 41 are cancelled. Claims 26 and 28-40 are pending and under examination.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 26 and 28-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hung et al. (Nat. Immun. Cell Growth Regul., 1990; 9(3): 160-164.) in view of Davis et al., U.S. Patent No. 4920209.
4. Claims 26, 28-31 and 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chanda et al. (Int. Rev. Immunol., 1990; 7(1): 67-77. or Virology, 1990; 175: 535-547; in the alternative) in view of Davis et al., U.S. Patent No. 4920209.

In response to the rejection set forth in the prior office action, Applicant submits that Applicant's is the first to demonstrate protection of non-human primates against HIV-1 challenge. Applicant further submits that neither Hung et al. nor Chanda et al. perform similar study in dogs with the Ad7-evn constructs; thus, there is no in vivo data in the references to suggest that eh vector would in fact elicit an immune response in dogs or any other animals. Applicant also asserts that the references do not teach or suggest administering gone or more intranasal or intramuscular booster dosages of the

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vector as claimed. Applicant also asserts that the obviousness analysis provided by the Examiner is an "obvious to try" rejection.

Applicant's submission has been considered, however, it is not found persuasive for the following reason(s):

i) In response to Applicant's "obvious to try" argument, Applicant is reminded that a prima facie showing of obviousness is based upon what the disclosure taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 U.S.P.Q. 209 (C.C.P.A. 1971). The reference is evaluated by what it suggests to one versed in the art, rather than by its specific disclosure. In re Bozek, 163 U.S.P.Q. 545 (C.C.P.A. 1969). Moreover, in the instant, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to optimize the immunization regimen, i.e., vaccine formulation, dosage, routes of immunization, etc., to produce a strong immune response.

ii) Additionally, while Applicant is correct to note that neither Hung et al. nor Chanda et al. perform similar study in dogs with the Ad7-env constructs; however, such performance is not required of Hung et al. and Chanda et al. In the instant, Hung et al. and Chanda et al. clearly teach that the vector constructs are viable in vivo. Thus, the administration of a vector construct that expresses an HIV glycoprotein would necessarily invoke an immune response against HIV because it is well known in the HIV art that HIV-1 envelope glycoprotein is highly immunogenic. A true mimic of the envelope would necessarily induce an immune response against HIV. Furthermore, Applicant is reminded that patentability determination is not made solely on the basis of

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the first to invent. Ergo, Applicant's proclamation that Applicant is the first to demonstrate protection of non-human primates against HIV-1 challenge is moot. In the instant, Hung et al. and Chanda et al. teach the composition employed in the claimed method, demonstrates that the vector construct is viable, and suggests the use of the composition to induce an immune response against HIV.

***Conclusion***

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

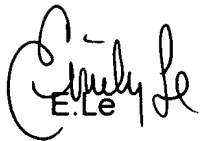
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



E. Le



Jeffrey S. Parkin, Ph.D.  
Primary Patent Examiner  
Art Unit 1648